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APPLICATION NO	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO	CONFIRMATION NO
09/731,457	12/06/2000	Ian Popoff	RTS-0182	1220

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EXAMINER
SCHULTZ, JAMES

ART UNIT	PAPER NUMBER
1635	12

DATE MAILED: 11/01/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Application No.	Applicant(s)
09/731,457	POPOFF ET AL.
Examiner	**Art Unit**
J. Douglas Schultz	1635

Office Action Summary

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 August 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2, and 4-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2 and 4-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
4) ☐ Interview Summary (PTO-413) Paper No(s) _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other

FILE

DETAILED ACTION

Response to Arguments

Applicants' arguments regarding claims 16-20 are noted, but are moot in view of their cancellation.

Claims 1, 2, and 4-14 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Dualan et al., in view of Taylor et al., Milner et al., Baracchini et al, and Hayes et al. for reasons of record. Applicant's arguments filed August 2, 2002 have been fully considered but they are not persuasive. Applicants argue that the sequence disclosed by the examiner's primary reference Dualan et al. is not the same sequence as the presently claimed target of SEQ ID NO 3. The applicants argue that the secondary reference of Taylor et al., while teaching that antisense can be designed to inhibit genes of known sequence, does not indicate whether a specific antisense sequence will be successful in inhibiting that gene, and that it is only through testing that such inhibitory activity can be ascertained. Applicants also argue that Dualan et al., and the secondary references of Taylor et al., Milner et al., Baracchini et al, and Hayes et al. do not teach or suggest antisense compounds to said target (damage-specific DNA binding protein 1, p127, or DDB1), and as such do not teach the limitations of the claims.

As to whether the polynucleotide sequence cited by the examiner is actually the presently claimed target of SEQ ID NO. 3, which Applicants indicate is GenBank accession number NM_001923.1, and thus different from the examiner's cited GenBank accession number U18299, it is pointed out that they are, in fact, identical sequences. Please see attached sequence printouts for the above GenBank accession number, and note that they are identical in both sequence and length. Under the "Comments" section for NM_001923, it is indicated that

NM_001923 is a provisional identifier, as it has not been reviewed by NCBI, and that is derived from U18299.1. Therefore, although the GenBank accession numbers are different, the targets are identical, and thus Dualan et al. discloses the target sequence of the instant SEQ ID NO. 3.

Applicants argue that Taylor et al., while teaching that antisense can be designed to inhibit genes of known sequence, does not state that such antisense are expected to inhibit gene expression, and that it is only through testing that such inhibitory activity can be ascertained. The language of the present claims is drawn to the genus of all polynucleotides 8 to 50 in length that have the broad functional limitation of inhibiting the target sequence. In rejecting the claims of the above under 35 U.S.C. 103 in the previous Office action, a prima facie case was established by the examiner whereby the burden of proof in showing that the claimed compounds are not obvious over the prior art as stated lies with the applicant, as per MPEP 2112.01:

> Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the prima facie case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. *In re Best*, 562 F.2d at 1255, 195 USPQ at 433.

Also, as per MPEP 2112:

> "[T]he PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his [or her] claimed product. Whether the rejection is based on inherency' under 35 U.S.C. 102, on prima facie obviousness' under 35 U.S.C. 103, jointly or alternatively, the burden of proof is the same...[footnote omitted]." The burden of proof is similar to that required with respect to product-by-process claims. *In re Fitzgerald*, 619 F.2d 67, 70, 205 USPQ 594, 596 (CCPA 1980) (quoting *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433-34 (CCPA 1977)).

Thus, in the absence of evidence to the contrary, the antisense compounds of the above claims are considered obvious as outlined above. Taylor et al. clearly indicate (para. 1, pg. 562) that antisense technology "can be designed to inhibit any gene target provided that the sequence is known." Because the present claims are product claims that are drawn broadly to the class of

compounds that are antisense to and inhibit the expression of the target, and because the compounds themselves are obvious as discussed in the prior Office action, and further since the Office does not have the capacity to test which of the compounds would have the claimed activity, the arguments provided do not persuasively demonstrate that the instantly claimed products are not obvious.

Applicants' arguments that each reference individually does not teach or suggest antisense oligonucleotides 8-50 nucleobases in length targeted to damage-specific DNA binding protein 1, P127 is not persuasive. In response to applicants' arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). As discussed in the previous Office action, motivation is provided by Hayes et al., who states that DDB1 is implicated in the repair of damaged DNA. Since damaged DNA is a root cause of many diseases including cancer, elucidating the function of such a gene would be scientifically and medically valuable. Thus motivation is clearly found in the prior art as stated in the prior Office action, and was not gleaned from the specification as Applicants allege.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. Douglas Schultz whose telephone number is 703-308-9355. The examiner can normally be reached on 8:00-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on 703-308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

J. Douglas Schultz, PhD
October 29, 2002

ANDREW WANG
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600